REMARKS

Claims 11-25 and 27-38 are pending. Applicants cancelled claims 1-10 and 26 without prejudice or disclaimer and reserve the right to pursue the cancelled subject matter in the future. Claim 11 has been amended to include the phrase, "and wherein the polymer composition is curable at a temperature of 30°C". Support for this recitation is located, for example, on page 21, lines 8-13 of the application as filed, where it states that the curing cross linking reaction can be carried out at temperatures ranging from 20 to 30°C. Applicants have amended claim 22 so that the phrase "sodium chloride type salts" reads "sodium chloride," as described below in response to the rejection under 35 U.S.C. § 112. Entry of the amended claims is kindly requested as the amendments place the application in condition for allowance and in better form for appeal. No new matter has been added into the claims.

Response to Rejection Under 35 U.S.C. § 112

Claim 22 has been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for use of the phrase "sodium chloride type salts." Applicants have amended claim 22 so that the term "sodium chloride type salts" reads "sodium chloride." Accordingly, the rejection no longer applies and should be withdrawn.

Response to Rejection Under 35 U.S.C. § 102

Claims 11-12 and 19-22 have been rejected under 35 U.S.C. § 102(b) as being anticipated by LaBelle *et al.* (US 4,412,033). In addition to the reasons set forth in applicants' July 31, 2009 response (which are incorporated herein by reference in their entirety), the rejection is improper because LaBelle *et al.* does not describe every element of the instant claims. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987).

The rejection is improper because LaBelle *et al.* does not provide a polymer composition that is "curable at a temperature of 30°C" nor does it provide "biodegradable' and

"biocompatible" compositions, as provided by the instant claims. *See* Declaration Under 37 C.F.R. § 1.132 of Pathiraja Gunatillake (hereafter "Declaration of Pathiraja Gunatillake"), para. 11. The polymer compositions of LaBelle *et al.* require curing temperatures much higher than 30°C. LaBelle *et al.* states, "the prepolymer composition is curable at temperatures above 60°C (preferably above 85°C)." *See* column 3, lines 42-44 of LaBelle *et al.* It goes on to explain that a key aspect of the invention relates to a two phase system in which one phase is not readily soluble in the other but, "upon heating to a temperature above 60°C, preferably above 85°C, the curing reaction is started." *See id.,* column 5, lines 30-42. Furthermore, the examples in LaBelle *et al.* use curing temperatures from between 260°F (127°C) and 350°F (166°C)—far above 30°C. Because LaBelle *et al.* does not describe polymer compositions that are curable at 30°C it cannot anticipate the claims.

Additionally, LaBelle *et al.* does not provide "biodegradable" and "biocompatible" compositions as recited by the instant claims. *See* Declaration of Pathiraja Gunatillake, para. 19. Although the terms "biodegradable" and "biocompatible" appear in the preamble of the claims, the terms must be afforded patentable weight due to applicants' reliance on them to define the claimed subject matter. "[C]lear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention". *Catalina Mktg. Int'l v. Coolsavings.com, Inc.*, 289 F.3d 801, 808-09 (Fed. Cir. 2002).

The compositions of LaBelle *et al.* are described as adhesives, coatings, sealants and the like. *See* abstract of La Belle *et al.* Specifically, the compositions of LaBelle *et al.* are used in automotive repair applications and to bond aluminum sheet molding to itself. *See* the examples of LaBelle *et al.* Compositions for industrial use (such as use in automotive repair) are designed to withstand degradation (as opposed to the claimed subject matter, which is biodegradable). Furthermore, "biocompatible" compositions, unlike compositions for industrial use, must be safe for administration inside the body. Care must be taken to avoid toxicity. For example, with respect to solvents, the specification explains that it is "especially important in biological applications" to be aware of solvents because "many solvents are not biocompatible and may, in

fact, be toxic to cell sustainability." *See* paragraph [0028]. Because LaBelle *et al.* does not describe "biodegradable" and "biocompatible" compositions, the references cannot anticipate the claims. Therefore, the rejection should be withdrawn.

Response to Rejection Under 35 U.S.C. § 103

Claims 11-12, 14 and 19-22 have been rejected under 35 U.S.C. § 103(a) as being obvious over LaBelle *et al.* in view of Mülhaupt *et al.* (US 4,908,406). In addition to the reasons set forth in applicants' July 31, 2009 response (which are incorporated herein by reference in their entirety), the rejection is improper because:

(1) The references do not account for every element of the claims;

(2) Modifying the prior art according to the claims renders the prior art unsatisfactory for its intended purpose; and

(3) The processes described in the prior art does not produce the claimed compositions.

The references do not account for a polymer composition that is "curable at a temperature of 30°C" nor do they account for "biodegradable" and "biocompatible" compositions. To establish *prima facie* obviousness, all the claim limitations must be accounted for. The Board of Patent Appeals and Interferences recently stated:

> When determining whether a claim is obvious, an examiner must make a searching comparison of the claimed invention – *including all its limitations* – with the teaching of the prior art." Thus, "obviousness requires a suggestion of all limitations in a claim." Moreover, as the Supreme Court recently stated, "*there must be some articulated reasoning* with some rational underpinning to support the legal conclusion of obviousness."

In re Wada and Murphy, Appeal 2007-3733 (Bd. Pat. App. & Inter. 2008) (internal citations omitted, underline added).

The instant claims are directed to polymer compositions that are curable at a temperature of 30°C (*i.e.*, the claimed compositions are capable of being cured at temperatures as low as 30°C). As explained above, LaBelle *et al.* describes compositions that must be cured at higher

temperatures. It states, "upon heating to a temperature above 60°C, preferably above 85°C, the curing reaction is started." *See* LaBelle *et al.,* column 5, lines 30-42. A prior art reference that teaches or suggests a preferred embodiment different from the claimed subject matter weighs against a determination of obviousness. *In re Baird*, 16 F.3d 380, 382-83 (Fed. Cir. 1994); *See* also MPEP 2144.08(II)(A)(4).

Mülhaupt *et al.* also requires curing temperatures much higher than 30°C. It explains, "[c]uring of the mixtures according to the invention takes place at elevated temperatures. In general, curing temperatures between 80° and 180°C., preferably between 100° and 140°C., are applied." See Mülhaupt *et al.*, column 5, lines 6-9. The examples of Mülhaupt *et al.* use curing temperatures of 140°C. Again, a prior art reference that teaches or suggests a preferred embodiment different from the claimed subject matter weighs against a determination of obviousness. *In re Baird*, 16 F.3d 380, 382-83 (Fed. Cir. 1994); *See* also MPEP 2144.08(II)(A)(4).

Applicants emphasize that the claimed compositions can be utilized *in vivo* because they are curable at 30°C. As explained in the Declaration of Pathiraja Gunatillake, the compositions of LaBelle *et al.* will not cure if applied to human tissue because the temperature of the human body is lower than 60°C. *See* Declaration of Pathiraja Gunatillake, para. 16. Curing the compositions of LaBelle *et al.* at 60°C in the human body would cause irreversible damage to the tissue. *See id.*

Because the references do not provide a composition that is curable at 30°C, and because they teach preferred embodiments different from the claimed embodiments, the rejection is improper and should be withdrawn.

Furthermore, the references do not account for a "biodegradable" and "biocompatible" composition. The compositions of LaBelle *et al.* and Mülhaupt *et al.* are described as adhesives, coatings, sealants and the like. *See* abstract of La Belle *et al.* and column 5, lines 55-64 of Mülhaupt *et al.* The compositions of LaBelle *et al.* are used in automotive applications and to bond aluminum sheet molding to itself. *See* the examples of LaBelle *et al.* Compositions for

industrial use (such as use in automotive applications) are designed to withstand degradation (as opposed to the claimed subject matter, which is biodegradable). Furthermore, "biocompatible" compositions, unlike compositions for industrial use, must be safe for administration inside the body. *See* Declaration of Pathiraja Gunatillake, para. 19. Care must be taken to avoid toxicity. *See id.* Furthermore, with respect to solvents, the specification explains that it is "especially important in biological applications" to be aware of solvents because "many solvents are not biocompatible and may, in fact, be toxic to cell sustainability." *See* paragraph [0028]. Because the references do not account for "biodegradable" and "biocompatible" compositions the rejection is improper and should be withdrawn.

The rejection is further improper because modifying the compositions of LaBelle *et al.* according to the instant claims renders the compositions unsatisfactory for their intended purpose. "If a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." *In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984); *See* MPEP § 2143.01.

As explained above, the compositions of LaBelle *et al.* and Mülhaupt *et al.* are described as adhesives, coatings, sealants and the like. *See* abstract of La Belle *et al.* Compositions of LaBelle *et al.* are used in automotive applications and to bond aluminum sheet molding to itself. *See* the examples of LaBelle *et al.* Modifying the compositions of LaBelle *et al.* so they are "biodegradable" and "biocompatible" would render them unsuitable for industrial use where the long term integrity of the composition is critical. Compositions used in automotive applications must withstand weathering and not degrade, in contrast to the claimed compositions, which must be biodegradable.

Furthermore, the instant claims provide that the compositions are curable at a temperature of 30°C; whereas the compositions of the prior art require curing at much higher temperatures. Failing to cure the compositions of LaBelle *et al.* and Mülhaupt *et al.* would also render them unsatisfactory for their intended purpose. Moreover, all of the examples in LaBelle *et al.* include plasticizers, e.g., HB-40, which is unsuitable for biomedical application and therefore not "biocompatible." *See* Declaration of Pathiraja Gunatillake, para. 19. Removing the HB-40 from

the compositions of LaBelle *et al.* (to make the compositions "biocompatible" according to the claims) would also likely render the composition unsatisfactory for their intended purpose.

Because modifying the prior art according to the instant claims destroys its intended purpose, the rejection is improper and should be withdrawn.

Finally, the process described in the prior art produces a different composition than claimed, as evidenced by the different physical properties of the prior art compositions. The Office Action mistakenly assumes that merely combining a cross-linking agent from Mülhaupt *et al.* with the compositions of LaBelle *et al.* will automatically afford the claimed compositions. The Office Action states:

> "[Mülhaupt *et al.*] teaches that methyl 2,6-diisocyanato hexanoate is known in the art as a compound which links a polyol and a polyhydroxy compound providing a cured polyurethane adhesive. [LaBelle *et al.*] and [Mülhaupt *et al.*] are both directed to preparing cured polyurethane adhesives. The rationale to incorporate methyl 2,6-diisocyanato hexanoate into the formulation of [LaBelle *et al.*] is (1) the compound is known to serve as a linker between polyols and polyhydroxy compounds to provide cured polyurethane adhesives and (2) it meets the structural and functional requirements taught by [LaBelle *et al.*], namely that it is aliphatic and has functionality greater than 1 but less than 4.

Office Action dated February 3, 2009, p. 7-8 (internal citation omitted).

The mere fact that a compound such as methyl 2,6-diisocyanato hexanoate can function as a cross-linking agent does not necessarily mean that incorporation of this cross-linking agent into the disclosure of LaBelle *et al.* will automatically result in the claimed compositions. *See* Declaration of Pathiraja Gunatillake, paras. 21-26. This is evident in that the compositions of LaBelle *et al.* are not curable at 30°C. Therefore, incorporation into LaBelle *et al.* of any reagent, without a teaching that the ability to cure at 30°C is critical, does not make the process of LaBelle *et al.* capable of forming the claimed compositions. As such, LaBelle *et al.*, even in view of Mülhaupt *et al.*, only teaches a process for making compositions that are formed under

conditions not recited in the instant claims and that have properties different from the claimed compositions.

In sum, the rejection is improper and should be withdrawn because the rejection fails to account for every elements of the claims, modifying the prior art to arrive at the claimed invention destroys its intended purpose, and the process described in the prior art produces a different composition than claimed.

Rejoinder

Claims 11-12, 14, and 19-22 are in condition for allowance. Claims 13 and 15-18 depend from and require all the limitations of claim 11 (claim 11 is a linking claim), and are therefore entitled to rejoinder upon allowance of claim 11. MPEP § 809 explains:

> When all claims directed to the elected invention are allowable, should any linking claim be allowable, the restriction requirement between the linked inventions must be withdrawn. Any claim(s) directed to the nonelected invention(s), previously withdrawn from consideration, which depends from or requires all the limitations of the allowable linking claim must be rejoined and will be fully examined for patentability.

Accordingly, applicants hereby exercise their right to rejoinder of claims 13 and 15-18.

Claims 23-25 and 27-38 are directed to processes/methods for making/using the elected subject matter and are therefore entitled to rejoinder upon allowance of claims 11-12, 14, and 19-22. *See* MPEP § 821.04(b) ("[w]hen all claims to the elected product are in condition for allowance, all process claims eligible for rejoinder must be considered for patentability.")

In preparation for rejoinder, applicants have cancelled claims 1-10 and 26 (claims not depending from linking claim 11) and ensured that claims 13, 15-18, 23-25 and 27-38 depend from and are commensurate in scope with claim 11 (and comply with the requirements of 35 U.S.C. § 112). Accordingly, applicants hereby exercise their right to rejoinder of these claims.

In view of the above, consideration and allowance are respectfully solicited.

In the event the Examiner believes an interview might serve in any way to advance the prosecution of this application, the undersigned is available at the telephone number noted below.

The Office is authorized to charge any necessary fees to Deposit Account No. 22-0185.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 22-0185, under Order No. 21444-00022-US from which the undersigned is authorized to draw.

Dated: February 25, 2010

Respectfully submitted,

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